Institutional Review Board

Guide for Research on Human Subjects
Faculty/Student Handbook

2005-06
Guidelines for Research on Human Subjects
FACULTY/STUDENT RESEARCH HANDBOOK 2005-06

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Guidelines for Research on Human Subjects

Introduction

Azusa Pacific University (APU) encourages the conduct of research in and among its schools, and in collaboration with other educational institutions, agencies, and organizations. The University, while respecting the right of faculty and students to full academic freedom in research, is firmly committed to adhering to the basic ethical principles underlying the acceptable conduct of research involving human subjects.

Adherence to the Common Rule: On June 18, 1991, seventeen Federal Departments and Agencies adopted a common set of regulations known as the Federal Policy for the Protection of Human Subjects or “Common Rule.” See http://www.hhs.gov/ohrp/ (Regulations 45 CFR 46). These federal regulations require that any institution requesting and receiving funds from a federal department or agency for research involving human subjects must assure that research is reviewed and approved by the University’s Institutional Review Board (IRB). The design of these regulations is based on established, internationally recognized ethical principles discussed in the Belmont Report (1979) as follows:

- **Respect for persons** incorporates at least two ethical convictions: “first, that individuals should be treated as autonomous agents; and second, that persons with diminished autonomy are entitled to protection” (thus, the need to obtain informed consent).

- **Beneficence** entails treating persons “in an ethical manner not only by respecting their decisions, but also by making efforts to secure their well-being. . . Two general rules: (1) do no harm; and (2) protect from harm by maximizing anticipated results and minimizing possible risks of harm.”

- **Justice** requires that the “benefits and burdens of research be distributed fairly” (thus, the principle of justice is applied in the selection of research subjects).


Official Definitions of Research and Human Subjects

- **Research** is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (§ 45 CFR. 46.102 [d]). (For the current Code of Federal Regulations, please see: <http://www.hhs.gov/ohrp/>)

A project or study is research if it:
- ✓ is conducted with the intention of drawing conclusions that have some general applicability, and
- ✓ uses a commonly accepted scientific method.
Research not requiring an application to the IRB:

Research within a classroom at APU
(a) using public, pre-existing, or simulated datasets in which individuals cannot be identified
(b) the results of which will not be published, presented or otherwise disseminated beyond the class may under certain circumstances be excluded and not filed with the IRB. (Levine & Skedsvold, 2003),

For an expanded list and explanation of potential excluded research, i.e.:
- Public databases
- Oral history research
- Certain student research projects
- Classroom research using public, pre-existing, or simulated data sets
- Hands-on APU classroom research
- Research involving minors (with consent by the administrator responsible for the unit in which students are enrolled)
(See Appendices, pp. 37-38)

Human Subjects are “living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information” (§ 45 CFR 46.101[f]).

If either of these two conditions applies, and if the project or study qualifies as research, then institutional approval is needed before any work is undertaken (Steneck, 2004, p. 39).

For additional Definitions of Terms, see Glossary

The Institutional Review Board

Purpose: The IRB provides an opportunity and place for individuals with different backgrounds to discuss and make judgment about the acceptability of projects, based on the criteria set out in the Common Rule. Members of the IRB at APU are appointed and must have completed the following programmed instruction and receive subsequent certification: see Human Participant Protections Education for Research Teams:
http://cme.cancer.gov
Types of Research Related to Human Subjects

Research Exempt from Full Board Review

EXCLUDED vs. EXEMPT Research:

**Excluded** research does not require an application to the IRB. Examples include:

(a) research using of public, pre-existing, or simulate databases in which the individuals cannot be identified;
(b) except for research on vulnerable populations*, sensitive issues, or invasive procedures, classroom research projects designed to provide hands on experience or research training for students are excluded if the results of the research will not be published, presented or otherwise disseminated beyond the classroom; (See also Classroom Research, pp. 10-11)
(c) oral history research (see excluded research addressed on the previous page and in the appendices for further discussion).

Research on human subjects that is **Exempt** requires an application for institutional approval through either:

(a) approval by a faculty member who is certified, i.e. having completed the Human Participant Protections Education Programmed Instruction within the last two years and who is not an investigator or involved with the research, or
(b) application to the IRB. (See subsequent exempt categories and process for requesting project that are Exempt.)

* Vulnerable Populations:
All research that involves fetuses, pregnant women, prisoners, or groups who may have diminished capacity to provide consent or who may be high risk, must be provided full review.

See § 45 CFR 46.201 - 207, pregnant women;
46.300 - 306, prisoners;
46.401 - 409, children and minors (except as included under exempt and expedited categories)

Exempt Categories

Some studies on human subjects may be exempt from the need for institutional approval. As indicated below, descriptions of such research must nevertheless be filed with the university for periodic review by the Institutional Review Board. Exempt research applies to studies that fall into the following categories (see also Charts 1-7 in the appendix).

a. **Research conducted in established or commonly accepted educational settings**, involving normal educational practices, such as

1. research on regular and special education instructional strategies, or
2. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behaviors, unless:

1. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, and
2. any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.

NOTE: If the subjects are children or minors (under the age of 18 in CA), research involving interview or survey procedures and research involving observations of public behavior in which the researcher participates in the activities being observed are not exempt. However, research involving the use of educational tests and research involving observation of public behavior in which the researcher(s) do not participate in the activities being observed are exempt.


- Interview or survey procedures with adults that are anonymous or benign are exempt from Full Board Review.
- Interview or survey procedures that represent minimal risk (see page 7) require expedited review.
- Interview or survey procedures that involve more than minimal risk for vulnerable populations require Full Board Review (see page 9).
- Interview or survey procedures that involve more that minimal risk for sensitive subjects may also require Full Board Review (for examples, see page 5).

c. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under (b)(2) of this section, if:

1. the human subjects are elected or appointed public officials or candidates for public office, or
2. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter

d. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
e. **Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads**, and which are designed to study, evaluate, or otherwise examine:
   1. public benefit or service programs;
   2. procedures for obtaining benefits or services under those programs;
   3. possible changes in or alternatives to those programs or procedures; or
   4. possible changes in methods or levels of payment for benefits or services under those programs.

f. **Taste and food quality evaluation and consumer acceptance studies**:
   see specific source for section 6 (§ 45 CFR 46.101).

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**Examples of Sensitive Topics that May Require Full Board Review**

1. Sexual orientation, attitudes, preferences, or practices
2. Illegal or punishable conduct, including use of alcohol, drugs, or other addictive products
3. Information that could damage an individual’s financial standing, employability, or reputation
4. Information (usually in medical records) that could lead to social stigmatization or discrimination
5. Psychological well-being or mental health, including physical or mental abuse
6. Incest, rape, date rape, or sexual molestation
7. Genetic information
8. Religious orientation or views – Religion is just one example of a sensitive topic. As with all sensitive topics, the broader principle is whether or not there is a potential for harm if the data were revealed. Identifying religious orientation on a research project would not typically be considered a sensitive topic at Azusa Pacific University. However, it should be noted that there are many possible scenarios where religious research could be potentially harmful to the participant if confidential data were revealed.
9. Veteran or wartime experiences

Please note: The sensitive subjects listed above are examples and not an exclusive list.
**Process for Requesting Projects that are exempt from IRB Review:**

Decisions about whether studies are **exempt** from the requirements of the Common Rule must be made by the Institutional Review Board or by an APU faculty member holding a certificate of completion for *Human Participant Protections Education for Research Teams* that was completed within the last two years. **The decision regarding an exempt study involving human subjects may not be made by the investigator or faculty affiliated with the research** (Steneck, 2004, p. 41).

To complete the programmed instruction, see [http://cme.cancer.gov](http://cme.cancer.gov), *Human Participant Protections Education for Research Teams*. A certification of completion must be filed with the Office of the Vice Provost for Graduate and Adult Programs for a faculty member to approve exempted research.

**Please complete:**

a) a Project Description (see guidelines in the appendix) and  
b) one of the following APU forms for requesting an **exemption** (see appendix or IRB forms in APU public folders)

1. *Student Research Project* (Form B); or *Course Specific Student Research* (Forms K & L)  
2. *Faculty/Staff Research Project* (Form C)  
3. *Research Project by Person not Associated with APU* (Form D)

**Submission:**

Although individual certified faculty may grant approval, reports of research approved under the exempt category are submitted to the Office of the Vice Provost for Graduate and Adult Programs and reviewed at the regular IRB meetings.
**Expedited Review**

**Criteria for an Expedited Review**

Research that is not exempt may qualify for expedited review. Expedited review procedures refer to research involving no more than minimal risk to human subjects and may be used for minor changes in already approved research. (See charts 8-9 in the appendix.)

Criteria for IRB approval of expedited review include:

1. **Risks to subjects are minimized:**
   - (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
   - (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. **Risks to subjects are reasonable,** in relation to the anticipated benefits if any to subjects, and the importance of the knowledge that may be reasonably expected to result.

3. **Selection of the subjects is equitable.**

4. **Informed consent is sought** from each prospective subject or the subject’s legally authorized representative.

5. **Informed consent is appropriately documented.**

6. The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7. **Adequate provisions are made to protect the privacy of subjects** and to maintain the confidentiality of data.

Again, adequate safeguards must be included to protect the rights and welfare of some or all of the subjects who are likely to be vulnerable to coercion or undue influence, including children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons—all requiring full IRB review. The IRB has the authority to suspend or terminate the approval of research that is not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected harm to subjects (§45 CFR 46.111).
Research Categories for an Expedited Review

The follow categories generally require an expedited review. For further explanation, see http://www.hhs.gov/ohrp (see expedited review).

(1) Clinical studies of drugs and medical devices when either an investigational new drug application or an investigational device exemption application is not required.

(2) Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as per guidelines.

(3) Prospective collection of biological specimens for research purposes by noninvasive means, e.g., hair and nail clippings, excreta, skin swab, etc.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

(8) Continuing review of research previously approved by the convened IRB:
   (a) where
      (i) the research is permanently closed to the enrollment of new subjects;
      (ii) all subjects have completed all research-related interventions; and
      (iii) the research remains active only for long term follow-up of subjects; or
   (b) where no subjects have been enrolled and no additional risks have been identified; or
   (c) where the remaining research activities are limited to data analysis http://www.hhs.gov/ohrp (see expedited review).
**Process for requesting an Expedited Review**

**Please complete:**
- a) a Project Description (see guidelines in the appendix) and
- b) one of the following APU forms for requesting an **expedited review** (see appendix or IRB forms in APU public folders)
  1. **Student Research Project** (Form B)
  2. **Faculty/Staff Research Project** (Form C)
  3. **Research Project by Person not Associated with APU** (Form D)

**Submit:**
The Project Description and the Request for Review Form to the Office of the Vice Provost for Graduate and Adult Programs.

Expedited research may be approved by the chair of the IRB or by a designee of the chair. Approvals under expedited procedures are reviewed at the regular monthly IRB meetings.

**Full IRB Review**

**Criteria**
Research that involves more than minimal risk, or is not covered by the categories listed as exempt or expedited, requires full review. (See charts in the Appendix)

**Research on Vulnerable Populations:**

Again, all research that involves fetuses, pregnant women, prisoners, or groups who may have diminished capacity to provide consent or who may be high risk, **must** be provided full review. See § 45 CFR 46.201 - 207, pregnant women;

- 46.300 - 306, prisoners;
- 46.401 - 409, children and minors (except as included under exempt and expedited categories)

**Process for requesting a Full Board Review**

**Please complete:**
- a) a Project Description (see guidelines in the appendix) and
- b) one of the following APU forms for requesting a **full review** (see appendix or IRB forms in APU public folders)
  1. **Student Research Project** (Form B)
  2. **Faculty/Staff Research Project** (Form C)
  3. **Research Project by Person not Associated with APU** (Form D)

**Submit:**
The Project Description and the request for review form to the Office of the Vice Provost for Graduate and Adult Programs. The request will be reviewed at the regular monthly full IRB meetings.
Classroom Research

I. Excluded Classroom Research

Research that is conducted in the classroom setting for the purposes of “hands-on” experience can be excluded from IRB review. Excluded research means that the IRB is not notified that the research is being conducted. It is emphasized that classroom research is not necessarily excluded from IRB review by virtue of occurring as a “hands-on” learning experience within the classroom. There are conditions that must be met in order for the project to be excluded from review (see below in shaded box).

Once a project is determined to be excluded from IRB review, this means that the instructor is assuming responsibility and liability for the research project. The course instructor has thus assumed the duty to protect the research participant that the student will be using in his/her experiment. In situations involving research misconduct, the instructors are not likely to be held liable in situations where there were no foreseeable risks. If there are foreseeable risks, the instructor is strongly encouraged to advise the student to change the project to one that involves minimal risk. For studies that are particularly promising that exceed minimal risk, the project must be submitted to the IRB.

What conditions must be met for research to be excluded from IRB review:

a) The project does not involve Vulnerable Populations including minors (see exception next page);
b) The project does not involve Sensitive Issues (those issues that could reasonably cause harm if the confidential data were revealed, see p. 5);
c) The project does not involve Invasive Procedures;
d) The project does not exceed Minimal Risk” (i.e. those risks that are tolerated as part of the risk of normal daily living, see exempt research, pp. 3-4);
e) The student agrees not to present or publish his/her research project outside of Azusa Pacific University (e.g. local professional conferences).

Note: APU strongly encourages the publication and presentation of classroom research, however, the student must obtain IRB approval prior to submitting the project for publication or presentation.

f). The faculty instructor must have completed the Online Protection of Human Subjects training (see cme.cancer.gov) and filed the certificate with APU’s Vice Provost for Graduate Programs.

Research Involving Minors in Education Research: Education research that meets the requirements for hands-on APU classroom research that is excluded from IRB review may also be excluded if the student obtains and presents to the instructor a consent form or letter signed by the administrator responsible for the unit in which the students are enrolled. Such a provision, if a faculty member desires to use it, must be stated in the syllabus along with the description of the requirements for projects in that course. The faculty member should retain these forms or letters for three years.

Please direct all questions regarding classroom research to the Office of the Vice Provost (x2036) or to the Institutional Review Board Chair (x5522)
II. Exempt Classroom Research

Some classroom research involves human subjects that does not meet the conditions for being excluded from IRB review (see previous page). If so, the student may apply to the IRB for one of the following categories:

- exempt, expedited, or full review by completing Form B (see appendix);
- exemption for research in specific courses, e.g., School of Education’s required (see next section).

III. Exempt Action Research Specific for EDUC 589 A & B

Action research conducted as the capstone project in the EDUC 589 A & B, Research for Educators course, for the MA in Education degree in the Advanced Studies Department of the School of Education, are exempt from full IRB review. This type of research involves activities with students or within the school community that are part of the teacher’s assigned responsibilities to benefit students or the school.

APU teacher-researchers need to submit the IRB Application for Research, Form L (see appendix) to their course instructor who is certified to represent the APU IRB in approving the research (the course instructor must have a current certification for Human Participant Protection Education for Research Teams on file with APU’s Office of Vice Provost for Graduate Programs.) Once approved as exempt, the instructor will submit a signed copy of Form L to the director of the MA in Education: Teaching or Curriculum & Instruction in Multicultural Contexts programs accompanied by Form K (one form for an entire class; see appendix for form). These forms will be documented and kept on record in the Office of the Vice Provost of Graduate and Adult Programs and in the MA in Education program office. A second signed and approved copy will be returned to the student to be placed at the end of the final research project.

Note Regarding “Exclusion.” This section has discussed research that is excluded from the purview of an IRB. Please note that the term “exclusion” is also used in connection with IRB review to indicate that, although vulnerable populations require special consideration, it is unethical to exclude groups likely to benefit from research. The federal regulations speak in terms of equitable selection of subjects (45CFR, 111,1,3). The Belmont Report discusses fair distribution of the “burdens and benefits” of research.

Faculty Responsibilities

Faculty members must provide information to students on university policies and guidelines on human subjects research and develop class procedures in a manner that protects the privacy, dignity, and welfare of participants.

Informed Consent

No investigator may involve a human being as a subject in research covered by these policies unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative.

Basic Elements of Informed Consent

(1) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) a description of any reasonably foreseeable risks or discomforts to the subject;

(3) a description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) a disclosure or appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; *(see below for guidance for obtaining a Certificate of Confidentiality to protect identifiable research information from forced or compelled disclosure).

(6) for research involving more than a minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) an explanation of whom to contact for answers to pertinent questions about the research subjects’ rights, and whom to contact in the event of a research-related injury to the subject;

(8) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;

(9) informed consent must be documented by the use of a written consent form and signed by the subject or the subject’s legalized representative. A copy will be given to the person signing the form;

(10) the name, address, and telephone number of the principal investigator of the research project, and his/her affiliation with Azusa Pacific University. If the principal investigator is a student, the name and telephone number of the faculty advisor is also required;

*Certificates of Confidentiality are issued by the National Institutes of Health (NIH) and other HHS agencies to protect identifiable research information form forced or compelled disclosure. Certificates of Confidentiality protect subjects from compelled disclosure of identifying information but do not prevent the voluntary disclosure of identifying characteristics of research subjects. Researchers, therefore, are not prevented from voluntarily disclosing certain information about research subjects, such as evidence of child abuse or a subject’s threatened violence to self or others. However, if a research intends to make such voluntary disclosures, the consent form should clearly indicate this.

* Please see http://www.hhs.gov/ohrp/humansubjects/guidance/certconf.htm
(11) a statement informing the subject that inquiries regarding the nature of the research, his/her rights as a subject, or any other aspect of the research as it relates to his/her participation as a subject can be directed to the Office of the Vice Provost for Graduate and Adult Programs at Azusa Pacific University; (§ 45 CFR 46.116). See Appendix or APU’s public folders for APU’s Informed Consent Checklist, Form E)

(12) **California Experimental Subject’s Bill of Rights** - if human subjects are involved in an experimental clinical procedure (See Form F);

(13) **Authorization for Use of Private Health Information** - if personal information considered “Protected Health Information” is used in the study (See Form G).

**Additional Elements of Informed Consent**

When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) a statement that the particular treatment of procedure may involve risks to the subject (or to the embryo or fetus) if the subject is or may become pregnant which are currently unforeseeable;

(2) anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent;

(3) any additional costs to the subject that may result from participation in the research;

(4) the consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) a statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject; and

(6) the approximate number of subjects involved in the study (§ 45 CFR 46.116).
Documentation of Informed Consent

1. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

   a. that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; or

   b. that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

2. Except as provided in paragraph 1 above, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject’s legally authorized representative. A copy shall be given to the person signing the form.

3. Except as provided in paragraph 1 of this section, the consent form may be either of the following:

   a. A written consent document that embodies the elements of informed consent required by §46.116 above. This form may be read to the subject or the subject’s legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

   b. A short written consent document stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject’s legally authorized representative. When this method is used, there shall be a witness to the oral presentation. (See §46.117 for additional related regulations.)
Researcher’s Continuing Responsibilities:

Continuing Responsibilities

Once a project has been approved by the IRB, researchers must adhere to the approved protocol and follow any additional IRB instructions. The continuing responsibilities include:

✓ enrolling only those subjects that meet IRB approved inclusion and exclusion criteria;
✓ properly obtaining and documenting informed consent;
✓ obtaining prior approval for any deviation from the approved protocol;
✓ keeping accurate records;
✓ **promptly reporting to the IRB any unanticipated problems involving risks to subjects or others** (Steneck, 2004, pp. 44-45).

Request for Change or Modification: Researchers must submit requests in writing for any change or modification to the approved research protocol to the IRB.

Maintaining Confidentiality

*Confidentiality* pertains to the treatment of information an individual has disclosed in a relationship of trust and with the expectation that it will not, without permission, be divulged to others in ways that are inconsistent with the understanding of the original disclosure. Researchers ordinarily use information participants have disclosed or provided voluntarily (i.e., with their informed consent) for research purposes. In most research, ensuring confidentiality can occur by following routine practices:

- Substituting codes for identifiers or encrypting identifiable data
- Removing face sheets (containing identifiers such as names and addresses) from survey instruments containing data
- Properly disposing of computer sheets and other papers
- Limiting access to identifiable data
- Educating the research staff on the importance of confidentiality
- Storing paper records in locked cabinets or assigning security codes to computerized records

(See [http://cme.cancer.gov/c01/b05_04.htm](http://cme.cancer.gov/c01/b05_04.htm))

Recording Data

In recording data, keep two simple rules in mind to avoid problems later, should someone ask about or question your work:

- Hard-copy evidence should be entered into a numbered, bound notebook so that there is no question later about the date the experiment was run, the order in which the data were collected, or the results achieved. Do not use loose-leaf notebooks or simply collect pages of evidence in a file. Do not change records in a bound notebook without noting the date and reasons for the change.
- Electronic evidence should be validate in some way to assure that it was actually recorded on a particular date and not changed at some later date. It is easy to change dates on computers and thereby alter the date a particular file seems to have been created. If you collect your data electronically, you must be able to demonstrate that they are valid and have not been changed.

As you record your data, it may be helpful to think about them as the legal tender of research – the currency researchers cash in when they apply for grants, publish, are considered for promotion, and enter into business ventures. To have and hold their value, research data must be properly recorded. (Steneck, 2004, pp. 92-93)
Retention and Storage of Data

The responsible handling of data begins with proper storage and protection from accidental damage, loss or theft:

- Lab notebooks should be stored in a safe place.
- Computer files should be backed up and the backup data saved in a secure place that is physically removed from the original data.
- Samples should be appropriately saved so that they will not degrade over time.
- Care should be taken to reduce the risk of fire, flood and other catastrophic events (Steneck, 2004, pp. 93-94).

Storing data that are subject to privacy restrictions must be stored in a safe place that is accessible only to authorized personnel. Private information can further be protected by using random codes to identify individual subjects, rather than names or social security numbers. Access to these codes can then be restricted to provide a double layer of protection. Whatever the method used to protect private or confidential information, the researcher who collects or uses the information has the primary responsibility for its protection. (Steneck, 2004, pp. 93-94)

Data should be retained for a reasonable period of time to allow other researchers to check results or to use the data for other purposes. There is, however, no common definition of a reasonable period of time. NIH generally requires that data be retained for 3 years following the submission of the closure report. Some government programs require retention for up to 7 years. APU requires that data be kept for 3 years after the closure report unless a longer retention is required by a specific agency. Before throwing out notebooks, cleaning out files, or erasing your computer memory, give careful consideration to who might benefit from or ask to see your data in the future. (Steneck, 2004, pp. 94-95)

Renewals for Continuing Research (See Form H in the Appendices)

Researchers must submit annual renewals for their continuing research. Depending on the degree of risk involved, more frequent reporting may be requested by the IRB (§ 46.109.e). For research that initially required a full IRB review, the following report must be submitted to the full IRB and satisfied for continuing approval. If the initial approval was an expedited review procedure, only the IRB Chair (or designated IRB member) receives the report. For both reports, address:

a. Project title, principal investigator, date of last IRB approval
b. Risks and potential benefits
c. Informed consent
d. Safeguards
e. A protocol summary and a status report on the progress of the research, including:
   • Data completion
   • Data collection in process
   • Data anticipated this year
   • The number of subjects accrued
   • A summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review;
   • A summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review;
   • Any relevant multi-center trial reports;
• Any other relevant information, especially information about risks associated with the research, and
• A copy of any newly proposed consent document.

At least one member of the IRB (i.e., a primary reviewer) also should receive a copy of the complete protocol including any modifications previously approved by the IRB. The IRB must determine if the currently approved informed consent document is still accurate and complete. 


Reporting Incidents

If research is conducted by an agency that has adopted the Common Rule or is covered by Federalwide Assurances, any unanticipated problems involving risks to subjects and others, any serious or continuing noncompliance with policies, or any suspension or termination of IRB approval of all non-exempt human subject research must be promptly reported by APU to the Office for Human Research Protections. 


Closure Report of Research Study (See Form J in the Appendices)

At the completion of the research study, submit the following written report to the IRB:

a. Project title, principal investigator, date of last IRB approval
b. The number of subjects studied
c. A summary of the following since the last IRB review including:
   • any adverse events and any unanticipated problems involving risks to subjects
   • any withdrawal of subjects from the research
   • any complaints about the research
   • brief summary of the research finding
The Institutional Review Board

Membership:

APU follows the guidelines of the Common Rule that requires the IRB to have at least five members who are of varying backgrounds and experience, including a diversity of race and gender. The IRB will also be comprised of at least:

- one scientist,
- one non-scientist, and
- “one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution” (45 CFR 46.107[d]).

In addition to the five-member board, at least two alternate faculty members and an alternate community member will be appointed to assure adequate representation at scheduled monthly meetings. All members and alternate members must have completed the Human Participant Protections Education for Research Teams instruction to be appointed to the IRB. Certificates of completion for the latter will be placed on file in the Office of the Vice Provost for Graduate and Adult Programs. For a programmed instruction to receive certification, see: http://cme.cancer.gov, see Human Participant Protections Education for Research Teams.

Functions and Operations of the IRB:

Faculty members will be appointed yearly to the IRB by the provost’s administrative team in collaboration with the dean of the faculty’s School or College. The IRB will review proposed research at convened meetings (at least monthly) at which a majority of the members are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it will receive approval of a majority of those members present at the meeting (§ 45 CFR 46.108).

Responsibilities of the IRB:

The IRB is responsible for determining that all of the following requirements are satisfied:

- the welfare and rights of human subjects are adequately protected and informed consent given and documented;
- human subjects are not placed at unreasonable physical, mental, or emotional risk as a result of research;
- the importance of the research outweighs the risks to the subjects;
- the researcher(s) is/are qualified to conduct research involving human subjects;
- the selection of the subjects is equitable;
- the research plan makes adequate provision for monitoring the data collected to ensure the safety of the subject;
- adequate provisions have been made to protect the privacy of subjects and to maintain the confidentiality of data;
- conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year (§ 45 CFR 46. 109; 116; 117).

The IRB has the authority to approve, require modifications in (in order to secure approval), or disapprove all research activities. The IRB will also notify the investigators and APU vice-provost’s office in writing of its decision to approve or disapprove the proposed research, or of modifications required to secure IRB approval. If disapproval is decided, the IRB will include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.
**Research Misconduct**

“Successful professional self-regulation depends on conscientious community participation. For individual researchers, this means they must assume responsibility for their own actions, take misconduct seriously, and report apparent misconduct by other researchers” (Steneck, 2004, p. 22). Faculty and others involved in the research process are subject to the uniform definition of research misconduct.

**Research Misconduct Defined**

Research misconduct is the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- **Fabrication** is making up data or results and recording or reporting them.
- **Falsification** is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- **Plagiarism** is the appropriation of another person’s ideas, processes, results, or works without giving appropriate credit.

To be considered research misconduct, actions must:

- represent a “significant departure from accepted practices”;
- have been “committed intentionally, or knowingly, or recklessly”; and
- be “proven by a preponderance of evidence” (Steneck, 2004, p. 20-21).

**Allegations of Research Misconduct at APU** will be submitted to both the Vice Provost of Graduate and Adult Programs and the Dean of the School/College where the research study is in question. The Dean and Vice Provost will complete an initial inquiry to determine whether the allegations have merit and conduct a formal investigation to reach conclusions about the truth of the allegations.

*If the allegations are found to be true, the Provost and the General Counsel of the University will weigh the conclusions reached by the Dean and Vice Provost and impose administrative actions to redress the misconduct or take steps to vindicate the person charged.* (See Steneck, 2004, p.23).

An **Annual Report on Possible Research Misconduct** is filed with the Office of Research Integrity, Department of Health and Human Services, U.S. Public Health Service by the Office of the Vice Provost for Graduate and Adult Programs.

To protect both the whistleblower and the respondent, “the research misconduct allegations will not be made public until they have been fully investigated and confirmed”--unless the misconduct could pose a threat to public health or safety. Misconduct in a clinical trial, however, “must immediately be brought to the attention of the person heading the trial, the person with oversight authority, or both.” The Office of Research Integrity and the federal sponsor of the research must be notified immediately. “Research institutions and researchers must not in any way penalize or take action against individuals who report research misconduct in good faith” (Steneck, 2004, p. 22-23).
Specific Requirements for Inquiries, Investigations and Reporting Possible Misconduct

1) Inquiring immediately into an allegation of other evidence of possible misconduct. An inquiry must be completed within 60 calendar days of its initiation unless circumstances clearly warrant a longer period. A written report shall be prepared that states what evidence was reviewed, summarizes relevant interviews, and includes the conclusions of the inquiry. The individual(s) against whom the allegation was made shall be given a copy of the report of inquiry. If they comment on that report, their comments may be made part of the record. If the inquiry takes longer than 60 days to complete, the record of the inquiry shall include documentation of the reasons for exceeding the 60-day period.

2) Protecting to the maximum extent possible, the privacy of those who in good faith report apparent misconduct.

3) Affording the affected individual(s) confidential treatment to the maximum extent possible, a prompt and thorough investigation, and an opportunity to comment on allegations and findings of the inquiry and/or the investigation.

4) Notifying the Director of the Office of Scientific Integrity (OSI), in accordance with § 50.104(a) when, on the basis of the initial inquiry, the institution determines that an investigation is warranted, or prior to the decision to initiate an investigation if the conditions listed in § 50.104(b) exist.

5) Notifying the OSI within 24 hours of obtaining any reasonable indication of possible criminal violations, so that the OSI may then immediately notify the Department’s office of Inspector General.

6) Maintaining sufficiently detailed documentation of inquiries to permit a later assessment of the reasons for determining that an investigation was not warranted, if necessary. Such records shall be maintained in a secure manner for a period of at least three years after the termination of the inquiry, and shall, upon request, be provided to authorized HHS personnel.

7) Undertaking an investigation within 30 days of the completion of the inquiry, if findings from that inquiry provide sufficient basis for conducting an investigation. The investigation normally will include examination of all documentation, including but not necessarily limited to relevant research data and proposals, publications, correspondence, and memoranda of telephone calls. Whenever possible, interviews should be conducted of all individuals involved either in making the allegation or against whom the allegation is made, as well as other individuals who might have information regarding key aspects of the allegations; complete summaries of these interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.

8) Securing necessary and appropriate expertise to carry out a thorough and authoritative evaluation of the relevant evidence in any inquiry or investigation.

9) Taking precautions against real or apparent conflicts of interest on the part of those involved in the inquiry or investigation.

10) Preparing and maintaining the documentation to substantiate the investigation’s findings. This documentation is to be made available to the Director, OSI, who will decide whether that Office will either proceed with its own investigation or will act on the institution’s findings.
11) Taking interim administrative actions, as appropriate, to protect Federal funds and insure that the purposes of the Federal financial assistance are carried out.

12) Keeping the OSI apprised of any developments during the course of the investigation which disclose facts that may affect current or potential Department of Health and Human Services funding for the individual(s) under investigation or that the PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.

13) Undertaking diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed and also undertaking diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

14) Imposing appropriate sanctions on individuals when the allegation of misconduct has been substantiated.

15) Notifying the OSI of the final outcome of the investigation.

(42 CFR § 50.103) [http://ori.dhhs.gov](http://ori.dhhs.gov) (See Policies/Regulations/Statutes, see Regulations)
References


Glossary

U. S. Dept. of Education/Grants and Policy Oversight Staff


Definition of Terms

Note: Unless otherwise indicated, the sources for the following definitions include:

Assurance: A written, binding commitment filed with a Federal agency by an institution that wishes to conduct human research. The institution promises to comply with the applicable regulations governing human subject research and stipulates the procedures through which compliance will be achieved.

Child or Children: Persons who have not attained the legal age for consent to treatments or procedures involved in research under the applicable law of the jurisdiction in which the research will be conducted. Special rules and protections govern the participation of children in research. In California, the legal age for consent is 18 years.

Exempted Research: Exemption from further review. See list of six major exemptions listed subsequently is this document.

Expedited Review: Human subjects are involved with no more than minimal risk, and/or minor changes are made in previously approved research during the (one year or less) for which approval is authorized.

Review of proposed research is completed by the IRB Chair or a designated voting member or group of voting members rather than the entire IRB. The expedited proposals that have been approved are later reviewed by the full IRB Committee.

Full Review: A review of the research proposal by a 5-member IRB committee who hold IRB certification. In order to approve the research proposal, the IRB shall determine that all relevant criteria for approval are satisfied and must receive the approval of a majority of the members present at the meeting.

IRB Approval: The determination of the Institutional Review Board that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.

Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological tests.

Parent: A person’s biological or adoptive parent. In the conduct of research, the permission of the parent is generally necessary if the potential participant is a minor (under 18 years of age in CA).
Permission: The agreement of parents(s) or guardian(s) to the participation of their child or ward in research.

Principal Investigator: The scientist or scholar with primary responsibility for the design and conduct of a research project, including preparation of the research protocol.

Protocol: Documentation of research objective, design, methods, statistical methods, and organization—including any amendments made to the original document. The research plan must include provisions for the adequate protection of the rights and welfare of prospective subjects and ensure that pertinent laws and regulations are observed.

Research Misconduct: Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.


Vulnerable Populations: Individuals or groups who, by reason of disability, illness, age, other status exhibit diminished personal autonomy. Neither the Federal regulations nor ethical codes... proscribe inclusion of vulnerable person as research subjects. However, DHHS regulations mandate special justification for research involving fetuses, pregnant women, and human in vitro fertilization; prisoners; and children.
### Appendices

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Excluded Research

Not all research falls within the purview of the IRB. Such research is described below.

Public Databases

Research is excluded from IRB review if the only data used are public datasets in which individuals cannot be identified.

Examples of public databases include the following:
- Inter-University Consortium for Political and Social Research
- U.S. Bureau of the Census
- National Center for Health Statistics
- National Center for Educational Statistics
- Bureau of Labor Statistics

Education’s Datafiles include:
- California Department of Education
- Center for Postsecondary Research at Indiana University
- Higher Education Research Institute at UCLA

Oral History Research

The Office for Human Research Protection in the U.S. Department of Health and Human Services has determined that oral history interviewing projects are excluded from board review. This does not mean interviewing projects in general, but only those that fit within the definition of oral history. For further information, see the posting of the Oral History Association at http://omega.dickinson.edu/organizations/oha/org_irbquestion.html

Hands-On APU Classroom Research: With the exception of

a) Vulnerable populations,
b) Sensitive issues, or
c) Invasive procedures,

classroom research projects designed to provide hands-on experience or research training to students are not treated as research projects in this policy and do not require formal IRB review. As for research with public datasets, a brief description of the requirements for such a project is to be included with the course syllabus submitted to the program director or department chair.

Projects in this category are expected to be confined to the specific class and end at the termination of that class. If it is anticipated that the research project will be used in other classes or published or presented beyond the classroom, the project must be submitted to the IRB for review as provided in this handbook. Faculty members must provide information to students on university policies and guidelines on human subjects research and develop class procedures in a manner that protects the privacy, dignity, and welfare of participants (adapted from the Miami University Human Subjects Guidelines, 2003, August, p. 4, http://www.miami.muohio.edu, and adopted by the Azusa Pacific University Institutional Review Board, 10-20-04).
Exception for Research Involving Minors: Research not involving sensitive issues or vulnerable populations (prisoners, pregnant women and individuals with diminished capacity) and that will not be disseminated beyond the course or classroom may be excluded if the student obtains and presents to the instructor a consent form or letter signed by the administrator responsible for the unit in which the students are enrolled. Such a provision, if a faculty member desires to use it, must be stated in the syllabus along with the description of the requirements for projects in that course. The faculty member should retain these forms or letters for several years.

Note Regarding “Exclusion.” This section has discussed research that is excluded from the purview of an IRB. Please note that the term “exclusion” is also used in connection with IRB review to indicate that, although vulnerable populations require special consideration, it is unethical to exclude groups likely to benefit from research. The federal regulations speak in terms of equitable selection of subjects (45CFR, 111.1,3). The Belmont Report discusses fair distribution of the “burdens and benefits” of research.
Guidelines for the Description of the Research Project

The description of a new submission to the IRB must include the following items. The description should not exceed three to four pages. Avoid technical jargon, as the IRB must by law include people who may not be specialists in your academic discipline.

1. Title
2. Three to four sentence statement summarizing the projects.
3. Research question(s)

If the study involves two or more phases, e.g., quantitative and qualitative, the following items must be described for each phase.

4. Data source if not directly from participants (e.g., pre-existing database), indicating whether or not data are de-identified
   OR
   Sample: number, age, sex, criteria for selection method of recruiting, inducement to participate (if any)
5. Treatment (if any)
6. Data-gathering procedures
7. Plan to ensure privacy and confidentiality
8. Statement of foreseeable risks or distress to participants in treatment or data-gathering; if none, so state
9. Procedures for obtaining consent from agency that controls access of participants (if any) and from participants and/or their legally responsible representatives
   OR
   Request for waiver of written informed consent with justification
10. Plan to analyze and disseminate data
11. Explanation of reason for exempt or expedited status, if applicable

Attach a copy of each consent form and instrument (questionnaire, interview protocol, etc.) Submit two complete hard copies and an electronic copy to the Office of the Vice Provost for Graduate and Adult Programs.

If you are a faculty or staff member pursuing a degree at another institution, you must seek the approval of the IRB of the institution(s) in which the research and the data collection related to human subjects is located.
Categories EXEMPT from Full Board Review

Use these numbers on your application; see full descriptions in text

1. Research in educational settings using normal educational practices

2. Research with educational tests (cognitive, diagnostic, aptitude, achievement) or research involving survey procedures, interview procedures, or observation of behavior, except:
   - **Not exempt** if subjects will be identifiable and disclosure could be harmful to them
   - **Not exempt** if subjects to be surveyed or interviewed are minors (unless the research is student research and will not be disseminated beyond the course or classroom)
   - **Not exempt** if subjects to be observed are minors and researcher will participate in the public behavior

3. Research listed in #2 (tests, surveys, interviews, observations) and, regardless of the “not exempt” clauses in that paragraph, either subjects are candidates for, elected to, or appointed to public office or federal law requires permanent confidentiality of personally identifiable information

4. Research involving existing data, documents, or specimens if public available or there is no possibility of matching data to subjects

5. Research and demonstration projects related to public service or benefit programs

6. Taste and food quality evaluation and consumer acceptance studies
Categories that Qualify for Expedited IRB Review

Use these numbers on your application; see full descriptions in text

1. Clinical studies of drugs and medical devices when an application for some is not legally required

2. Collection of blood samples by methods indicated in the text

3. Prospective collection of biological specimens by noninvasive means

4. Collection of data through noninvasive procedures routine in clinical practice
   (If research involves general anesthesia or sedation, x-rays, or microwaves, a full review is required.)

5. Use of data, documents, records, or specimens collected solely for nonresearch purposes (e.g., medical treatment or diagnosis)

6. Collection of data from recordings made for research purposes

7. Research on human characteristics or behavior (cognition, social behavior, etc.)
   or
   research employing survey, interview, oral history, focus group, program evaluation human factors evaluation, or quality assurance methodologies

8. Continuing research, already approved by IRB, where there will be no new involvement of subjects except for long-term follow-up
   or
   no subjects have been enrolled and there are no new risk factors.
Please note that Form A (used during 2004-05) is no longer being used.
INSTITUTIONAL REVIEW BOARD (IRB) APPLICATION

Student/Classroom Research Project(s)  
(Form B)

Use this form a) for any individual student research project involving human subjects (independent study, capstone, thesis, dissertation, etc.), or  
b) for course or classroom research that is not excluded from full IRB review;  
c) for research in specific EDUC courses, see forms K and L, also in the appendix.

(For studies that required full review, please note that the IRB board meets once a month;
Student (if more than one, attach list of names with ID numbers and signatures)

(Please print) ___________________________________________ ID# __________________________

Phone __________________________ Email __________________________

Faculty Advisor (Please print) ___________________________________ Dept _____________

Phone __________________________ Fax __________________________ Email __________________________

Project Title __________________________________________

Type of Research (please check)

□ Classroom project          □ Master’s capstone or thesis
□ Independent study project □ Doctoral capstone, thesis, or dissertation
□ Other: __________________________

Submission Type (please check)

□ New                   □ Continuation
□ Addendum             □ Renewal
□ Other: __________________________

Research Start Date _________________ Expected End Date _________________

Recommendation for IRB Review Category (see IRB instructions)

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INSTITUTIONAL REVIEW BOARD (IRB) APPLICATION

Student Research Project (Form B) cont’d.

Assurance. The undersigned have reviewed the standards for exempt, expedited, and full review by the IRB and attach the complete project description required (see Project Description in IRB handbook appendices).

Signatures

Student _________________________________________________             Date ___________
(if more than one, attach assurance with list of names with ID numbers and signatures)

Faculty _________________________________________________             Date ___________

Department Chair _________________________________________            Date ___________

Submit two complete hard copies and an electronic copy to the Office of the Vice Provost for Graduate and Adult Programs

For IRB Use Only

☐ Preliminary approval (e.g., grant proposal, institutional research, including CFR 46.118). Re-submission required prior to data collection.

☐ Approved as exempt. No further review needed unless protocol changes.

Signature: Certified Faculty ___________________________________________ Date ____________
OR
Signature: IRB Chair or Designee ___________________________________________ Date ____________

☐ Approved as expedited. No further review needed unless the protocol changes or data-gathering extends beyond time limit.

Project approval expires ____________________________________________

Signature: IRB Chair or Designee __________________________________________ Date ____________

☐ Full Review

☐ Approved as submitted.

Project approval expires ____________________________________________

☐ Not approved (see attachment). Re-submission required.

Signature: IRB Chair ___________________________________________ Date ____________

Names of board members who reviewed this project

_________________________________     ________________________________
_________________________________     ________________________________

Please note: The Institutional Review Board (IRB) at Azusa Pacific University (APU) is charged with oversight of the protection of human subjects in experimental research. Receiving IRB approval does not constitute institutional approval of the project by APU. If the responsible investigator believes that the project might be inconsistent with the mission and values of APU or potentially not represent the University in a favorable light, it is recommended that the responsible investigator contact the Vice Provost for Graduate and Adult Programs.
INSTITUTIONAL REVIEW BOARD (IRB) APPLICATION

APU Faculty/Staff Research Project (Form C)

Use this form for any faculty or staff research project involving human subjects. For studies that require full review, be aware that the IRB board meets once a month.

Principal Investigator (Please print) ____________________________ Dept __________

Phone ____________ Fax ____________ Email ____________________________

(If there are other investigators, attach assurance with names and signatures)

Project Title ____________________________________________________________

Submission Type

□ New  □ Continuation
□ Addendum  □ Renewal
□ Other: _______________________________________________________________

Research Start Date ____________________ Expected End Date __________________

Recommendation for IRB Review Category (see IRB instructions)

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<td>□ Expressed because (number) ____________________________</td>
<td>□ Expedited</td>
</tr>
<tr>
<td>□ Full Review</td>
<td>□ Full Review</td>
</tr>
</tbody>
</table>

The undersigned have reviewed the standards for exempt, expedited, and full review by the Institutional Review Board and attach the complete information required (see IRB instructions).

Signatures

__________________________________________ Principal Investigator

(if there are other investigators, attach assurance with names and signatures)

__________________________________________ Supervisor

Continued on next page
INSTITUTIONAL REVIEW BOARD (IRB) APPLICATION
APU Faculty/Staff Research Project (Form C) (cont’d)

For IRB Use Only

☐ Preliminary approval (e.g., grant proposal, institutional research, including CFR 46.118). Re-submission required prior to data collection.

☐ Approved as exempt. No further review needed unless protocol changes.

  Signature: Certified Faculty ________________________________ Date ____________

OR

  Signature: IRB Chair or Designee ______________________________ Date ____________

☐ Approved as expedited. No further review needed unless protocol changes or data-gathering extends beyond time limit.

  Project approval expires ______________________________

  Signature: IRB Chair or Designee ______________________________ Date ____________

☐ Full Review

  ☐ Approved as submitted.

  Project approval expires ______________________________

  ☐ Not approved (see attachment). Re-submission required.

  Signature: IRB Chair ______________________________ Date ____________

Names of board members who reviewed this project

__________________________________     ______________________________
__________________________________     ______________________________

Please note: The Institutional Review Board (IRB) at Azusa Pacific University (APU) is charged with oversight of the protection of human subjects in experimental research. Receiving IRB approval does not constitute institutional approval of the project by APU. If the responsible investigator believes that the project might be inconsistent with the mission and values of APU or potentially not represent the University in a favorable light, it is recommended that the responsible investigator contact the Vice Provost for Graduate and Adult Programs.

Submit two complete hard copies and an electronic copy to the Office of the Vice Provost for Graduate and Adult Programs
INSTITUTIONAL REVIEW BOARD (IRB) APPLICATION

Research Project by Person not associated with APU (Form D)

Use this form for any research project involving human subjects. For studies that require full review, be aware that the IRB board meets once a month.

Principal Investigator (Please print) ____________________________________________________________________________

Address __________________________________________ City __________ State ___ ZIP _____

Phone ______________ Fax ______________ Email __________________________

(Institutional Affiliation & Address) ____________________________________________________________________________

If there are other investigators, attach assurance with names and signatures

Role □ Student □ Faculty □ Other: __________________________ Dept __________

If student, name of faculty advisor __________________________________________

Phone ______________ Fax ______________ Email __________________________

Project Title ____________________________________________________________________________

Submission Type

□ New □ Continuation □ Addendum □ Renewal □ Other: __________________________

Research Start Date __________________________ Expected End Date __________

Recommendation for IRB Review Category (see IRB instructions)

<table>
<thead>
<tr>
<th>This submission</th>
<th>If other than new, category of original submission</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Exempt because (number) ________________________</td>
<td>□ Exempt</td>
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<tr>
<td>□ Expedited because (number) ______________________</td>
<td>□ Expedited</td>
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<td>□ Full Review</td>
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</tbody>
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INSTITUTIONAL REVIEW BOARD (IRB) APPLICATION

Research Project by Person not associated with APU (Form D) (cont’d)

The undersigned have reviewed the standards for exempt, expedited, and full review by the Institutional Review Board and attach the complete information required (see IRB instructions).

Signatures

___________________________________________ Principal Investigator
(if there are other investigators, attach assurance with names and signatures)

___________________________________________ If student, Faculty Advisor

For IRB Use Only

Preliminary approval (e.g., grant proposal, institutional research, including CFR 46.118). Re-submission required prior to data collection.

Approved as exempt. No further review needed unless protocol changes.

Signature: Certified Faculty _____________________________ Date ____________

OR

Signature: IRB Chair or Designee _____________________________ Date ____________

Approved as expedited. No further review needed unless protocol changes or data-gathering extends beyond time limit.

Project approval expires _____________________________

Signature: IRB Chair or Designee _____________________________ Date ____________

Full Review

Approved as submitted.

Project approval expires _____________________________

Not approved (see attachment). Re-submission required.

Signature: IRB Chair _____________________________ Date ____________

Names of board members who reviewed this project

__________________________________ ________________________________

__________________________________ ________________________________

Submit two complete hard copies and an electronic copy to the Office of the Vice-Provost for Graduate and Adult Programs, Azusa Pacific University

Please note: The Institutional Review Board (IRB) at Azusa Pacific University (APU) is charged with oversight of the protection of human subjects in experimental research. Receiving IRB approval does not constitute institutional approval of the project by APU. If the responsible investigator believes that the project might be inconsistent with the mission and values of APU or potentially not represent the University in a favorable light, it is recommended that the responsible investigator contact the Vice Provost for Graduate and Adult Programs.
INSTUTIONAL REVIEW BOARD

Informed Consent Checklist (Form E)

When using humans as research subjects you must first obtain their informed consent. Use this checklist to effectively create an informed consent form. See also pp. 12-13.

☐ A statement explaining the purpose of the research
☐ A statement of the expected duration of the subject’s participation
☐ A description of the procedures to be followed
☐ A description of any reasonable foreseeable risks or discomforts to the subject, including invasion of privacy
☐ A description of any benefits resulting from the research, either to the subject or to others
☐ A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
☐ A statement that informs subject of his/her right not to be a subject in a research project that is also a teaching exercise
☐ A statement informing subject about how his/her anonymity will be guarded; i.e., that their confidentiality will be protected by assigned code numbers, by limitations of who has access to data, by data storage in locked cabinets, by locked computer files, etc.
☐ A statement that the subject’s participation is voluntary, and that his/her refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
☐ If research involves more than a minimal risk, explain whether any compensation or medical treatment is available if injury occurs and, if so, what they consist of, or where further information may be obtained.
☐ If written informed consent is required, a place for the subject to sign and date the form must be included. A statement that a copy of the signed consent form will be given to the subject for his/her records must also be included.
☐ If the subject is a minor, a statement of parental responsibility in consenting to the child’s participation in the study with a place for the parent to sign and date the form in addition to the participant’s signature.
☐ The name, address, and telephone number of the principal investigator of the research project, and his/her affiliation with Azusa Pacific University. If the principal investigator is a student, the name and telephone number of the faculty advisor is also required.
☐ A statement informing the subject that inquiries regarding the nature of the research, his/her rights as a subject, or any other aspect of the research as it relates to his/her participation as a subject can be directed to the Office of the Vice Provost for Graduate and Adult Programs at Azusa Pacific University.
☐ If clinical research involves human subjects,
   1.) a signed California Experimental Subjects Bill of Rights,
   2.) a signed authorization for Use of Private Health Information.
☐ Additional elements – please see listing in Faculty/Student Research Handbook.
CALIFORNIA EXPERIMENTAL SUBJECT’S BILL OF RIGHTS (Form F)

You have been asked to participate as a subject in an experimental clinical procedure. Before you decide whether you want to participate in the experimental procedure, you have a right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

I have carefully read the information contained above in the “California Experimental Subject’s Bill of Rights” and I understand fully my rights as a potential subject in a medical experiment involving people as subjects.

_________________________________  _______________________________________
Date                                           Patient

_________________________________  _______________________________________
Time                                           Parent/Legal Guardian

If signed by other than the patient, indicate relationship:

_________________________________  _______________________________________
Relationship                            Witness
The study named above may be performed only by using personal information relating to your health. National and international data protection regulations give you the right to control the use of your medical information. Therefore, by signing this form, you specifically authorize your medical information to be used or shared as described below.

The following personal information, considered “Protected Health Information” (PHI) is needed to conduct this study and may include, but is not limited to: Name, address, length and type of disability, any orthopedic injuries or cardiovascular disorders.

The individual(s) listed above will use or share this PHI in the course of this study to the Institutional Review Board (IRB) of Azusa Pacific University, the sponsor of the study and its affiliates, government agencies such as the Food and Drug Administration (FDA), other research sites involved in this study, health care providers who provide services to you in connection with this study, central labs, central review centers and central reviewers.

The main reason for sharing this information is to be able to conduct the study as described earlier in the consent form. In addition, it is shared to ensure that the study meets legal, institutional, and accreditation standards. Information may also be shared to report adverse events or situations that may help prevent placing other individuals at risk.

All reasonable efforts will be used to protect the confidentiality of your PHI, which may be shared with others to support this study, to carry out their responsibilities, to conduct public health reporting and to comply with the law as applicable. Those who receive the PHI may share with others if they are required by law, and they may share it with others who may not need to follow the federal privacy rule.
Subject to any legal limitations, you have the right to access any protected health information created during this study. You may request this information from the Principal Investigator named above but it will only become available after the study analyses are complete. The authorization expires upon the conclusion of this research study.

You may change your mind about this authorization at any time. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new personal health information will be used for this study. However, study personnel may continue to use the health information that was provided before you withdrew your permission. If you sign this form and enter the study, but later change your mind and withdraw your permission, you will be removed from the study at that time. To withdraw your permission, please contact the Principal Investigator or study personnel at (626) 815-2036.

You may refuse to sign this authorization. Refusing to sign will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are entitled. However, if you do not sign this authorization form, you will not be able to take part in the study for which you are being considered.

I agree that my personal health information may be used for the study purposes described in this form.

______________________________  __________________________
Signature of Patient or Patient’s Legal Representative  Date

______________________________
Printed Name of Legal Representative (if any)

______________________________  __________________________
Representative’s Authority to Act for Patient  Date

______________________________  __________________________
Signature of Person Obtaining Authorization  Date
INSTITUTIONAL REVIEW BOARD (IRB) APPLICATION

Request for Renewal of Continuing Research (Form H)

This form is used for continuing research that was initially approved by either an expedited or a full review by the IRB. This request must be submitted so that continuing approval may be received at least yearly or by the anniversary of the previous approval.

Current date ________________________________ Date of previous approval ________________

Project Title ____________________________ ID# ____________________________

Principal Instigator __________________________

Phone # ____________________________ Email ____________________________

If Student Project, Faculty Advisor’s Signature __________________ Date ____________

Department Chair’s Signature __________________ Date ____________

Since the previous approval (of one-year or less), please identify any of the following:

Please check one:

- Data collection completed OR
- Data collection in process

The number of subjects studied to date ________________________________

Changes in risks. If so, explain ____________________________________________

Changes in benefits to subject. If so, explain ____________________________________

Changes in informed consent/safeguards. If so explain ______________________________

Attach a summary of the following since the last IRB review:

a. any adverse events and any unanticipated problems involving risks to subjects
b. any withdrawal of subjects for the research
c. any complaints about the research
d. a summary of any relevant recent literature, interim findings, and amendments or modifications to the research
e. any relevant multi-center trial reports (if applicable)
f. a copy of the current informed consent document and any newly proposed consent document.
INSTITUTIONAL REVIEW BOARD (IRB) APPLICATION

Request for Renewal of Continuing Research (Form H) (cont’d)

For IRB Use Only

☐ Re-approved as expedited. No further review needed unless protocol changes or data-gathering extends beyond time limit.

Project approval expires ____________________________________________________

Signature: IRB Chair or Designee ____________________________ Date______________

☐ Re-approved Full Review

☐ Approved as submitted.

Project approval expires ____________________________________________

☐ Not approved (see attachment). Re-submission required.

Signature: IRB Chair ____________________________ Date______________

Names of board members who reviewed this project

__________________________________ ________________________________

__________________________________ ________________________________

Please submit two signed hard copies and an electronic copy of this request to the Office of the Vice Provost for Graduate and Adult Programs
INSTITUTIONAL REVIEW BOARD (IRB) APPLICATION

Closure Report of Research Study (Form J)

This form is used as a final report for continuing research that was initially approved by either an expedited or a full review by the IRB. (The information is utilized in the University’s annual report to the Office of Research Integrity.)

Date of most recent IRB approval or re-approval: ______________________________________

Project ID# and Title:
_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________

Principal Investigator ______________________________________________________________

Principal Investigator’s Phone #: ______________________________________________________

Principal Investigator’s e-mail ______________________________________________________

Please attach an explanation if any of the following occurred since the last approval (i.e. approval within one year or less),

a. any adverse events and any unanticipated problems involving risks to subjects (include dates reported)

b. any withdrawal of previously enrolled subjects from the research

c. any complaints about the research

I certify there were no changes in the protocol approved by the IRB:

Principal Investigator ____________________________ Signature Printed Name Date _________

If student project, Faculty Advisor ____________________________ Signature Printed Name Date _________

Department Chair ____________________________ Signature Printed Name Date _________

Dean ____________________________ Signature Printed Name Date _________

Please submit two signed hard copies and one electronic copy to the Office of the Vice Provost for Graduate and Adult Programs
Azusa Pacific University

INSTITUTIONAL REVIEW Board (IRB) APPLICATION
EDUC 589 A&B Capstone Research for Educators Course

APU Course Research Projects EXEMPT from Full Institutional Review - (Form K)

The attached research proposals involving human subjects meet the APU IRB criteria as exempt from full board review:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
   (i) research on regular and special education instructional strategies, or
   (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Instructor’s Name (please print)____________________________________ Term ________________

Phone ________________ Email ___________________________ Campus site____________________

Advanced Studies Department
Master of Arts in Education: Teaching and Curriculum & Instruction in Multicultural Contexts Programs

ECUC 589 A&B Capstone Research for Educators Course

Course Description:

EDUC 589-A: Research for Educators, Beginning Process 2 units
This advanced course enables teachers to become more informed users and designers of educational research. Teachers begin the process of planning and implementing their own classroom or school-based inquiry. Through activities integrated in their own research process, teachers will learn more about how to locate, value, and synthesize other relevant research; select and employ appropriate types of qualitative or quantitative methods of data gathering; and analyze a variety of descriptive data. Teachers will complete the process in EDUC 589-B

EDUC 589-B: Research for Educators, Capstone Reporting 1 unit
This course is a sequel to EDUC 589-A, enabling teachers to complete their own research inquiry process and submit a final research report. Teachers will work independently and will conference with a faculty member and peers in order to review fully their data analyses and results, and to revise and edit effectively their completed research reports.

☐ Exempt from review by the full Institutional Review Board (see IRB handbook)
I certify that within the past two years I completed or renewed the certificate required for authorization by APU to approve classroom research projects. I have reviewed the research plan(s) and instrument(s) in relation to IRB criteria, and find them to be exempt from full IRB board review. I have also reviewed the principles of protection of human subjects and the IRB categories with my students. As a representative of the APU IRB I approve these research study proposals.

Signature of Certified Faculty____________________________________ Date Certified____________________

Faculty Form
Azusa Pacific University
INSTITUTIONAL REVIEW Board (IRB) APPLICATION
ECUC 589 A&B Capstone Research for Educators Course – (Form L)

1. Project Title

2a. Name of student __________________________ ID Number _____________

2b. Term and Year ___________________________ Campus Site ___________

2c. Instructor’s Name ____________________________

3. Reason for exemption from full IRB review
The attached research proposal involving human subjects meets the APU IRB criteria as exempt from full board review:
   (1) Research conducted in established or commonly accepted educational settings, involving normal educational
       practices, such as
       (i) research on regular and special education instructional strategies, or
       (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or
            classroom management methods.

4. Purpose (include research question)


5. Subjects or participants (including criteria for selection)


6. Data-gathering procedures


7. Students may be required to obtain permission from an organization through which contacts or records are
   obtained. This is dependent upon the policies of the organization. In such a case, provide the name and
   address of the organization.

✓ Approved by Certified Faculty: __________________________ Date: ________

Submit two complete hard copies to the instructor:
   (1) approved copy will be submitted by the instructor to Youulanda Jenkins, Advanced Studies Dept., who will forward it to
       the office of the Vice Provost for Graduate and Adult Programs
   (2) approved copy will be returned to the student to be placed at the end of the completed research project.

Student Form